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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,707	03/21/2001	Hideji Tajima	10287.42	3289

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EXAMINER

CROSS. LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,707	Applicant(s) TAJIMA	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 17-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-11 and 13-15 is/are rejected.
- 7) ☒ Claim(s) 6-8,12 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5-16-02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-16 in the reply filed on April 26, 2004 is acknowledged. Claims 17-48 are withdrawn from consideration in this Office Action as being directed to non-elected subject matter.

Specification

At the paragraph bridging pages 26-27 in the specification, the phrase "projections 11a are mounted on the outer periphery along the circumference at" is repeated twice. Applicants should delete the second occurrence of the phrase. Also, on page 27, there appears that a sentence is missing from the last paragraph, since the last paragraph begins with "specific numerical value examples".

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Observations

It is appears that Applicants intended claim 15 to be dependent on claim 14, as opposed to claim 13, because of the similarities in subject matter.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1743

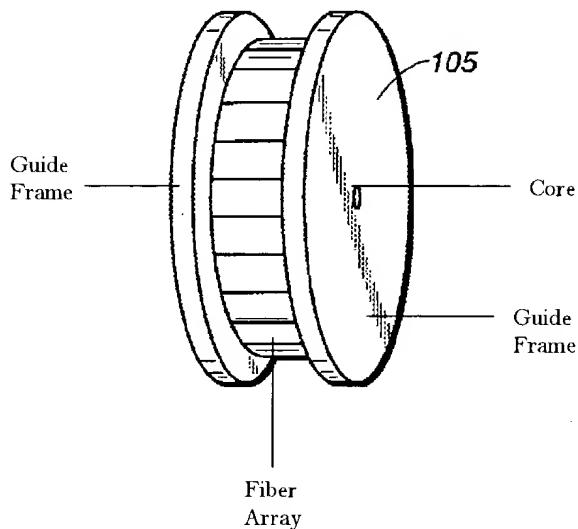
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-4, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,057,100 to Heynecker in view of US Patent 6,482,593 to Walt et al.

Heynecker discloses oligonucleotide arrays. The oligonucleotide arrays are fibers, which comprise a support having oligonucleotides attached thereto. Oligonucleotides are substances for detection of analytes in a sample. The fiber support is a base member to which the oligonucleotides are attached and is disclosed as being made from materials such as polyethylene (col. 3, lines 16-35). At col. 4, lines 14-15, Heynecker teaches that the fiber is "flexible". The arrays have at least two different oligonucleotides attached, preferably more than two (col. 4, lines 17-22). Heynecker further discloses that each oligonucleotide species is arranged in distinct linear rows (side by side) to form an immobilized oligonucleotide strip (col. 4, lines 47-56). Further, Heynecker discloses "spacer fibers" to aid in alignment. With respect to the supporting member of claims 3 and 4, Heynecker discloses a casing (105), similar to a reel, wherein the fibers are coiled around the core of the casing. The two end pieces of the casing are similar to Applicants' claimed guide frames. Heynecker discloses that the disks may be rotated through a solution of test sample (col. 6, lines 28-37).



Heynecker differs from the instantly claimed invention in that there is no disclosure of oligonucleotides are in a fixed location on the fiber, wherein the location corresponds with a particular chemical structure.

Walt et al teach biosensors for detecting oligonucleotide species in a fluid sample. the biosensors of Walt et al comprises an optical fiber (12) having oligonucleotides attached to the fiber strand (col. 13, lines 24-31). At col. 14, lines 62-64 and col. 15, lines 28-41, Walt et al teach that each oligonucleotide deposit on the fiber serves as one fixed probe immobilized at a predetermined spatial position. Further, Walt et al teach an identifying label, such as a dye, on the fiber to reflect the presence of a target species (col. 18, line 60 – col. 19, line 11).

It would have been obvious to one of ordinary skill in the art to have the oligonucleotides of Heynecker to be attached to the fiber at predetermined locations to allow detection at a particular location to determine the presence of a particular analyte in the sample. Where the oligonucleotides are positioned at specific locations on the fiber, the user need only

Art Unit: 1743

observe the presence of a reaction at that location to determine the presence of a particular analyte in the sample.

Also, Heynecker does not explicitly teach that the casing (105) is made of permeable material. However, such would have been obvious to one of ordinary skill in the art because the casing will be rotated through a sample solution. Thus, if the casing were made of permeable material, then it can be assured that the sample solution reaches the reaction sites on the fibers, providing for accurate detection.

5. Claims 9-11 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Heynecker in view of Walt et al as applied to claims 1-4, 14 and 15 above, and further in view of Japanese Publication 11-64322 to Kikuchi.

The disclosures of Heynecker and Walt et al are described above. With respect to the above mentioned claims, neither Heynecker nor Walt et al teach a feed support system.

Kikuchi teaches an apparatus for analyzing a test tape (2). The apparatus comprises a feed means (31), wind means (32), rollers (33, 34, 35). The feed means, wind means and rollers constitute the feed support section. The rollers presumably have a belt that aids in advancing the test tape along. The feed means is a supply reel and the wind means is a take up reel. The feed support moves the test tape into a reaction tank (4) and pass the analyzer/detection region (7) for detection. Kikuchi further teaches a cartridge having a rotating part for dispensing the test tape. When used in the feed support system, the cartridge provides a coupling for feeding the test tape. It would have been obvious to one of ordinary skill in the art to use the apparatus of Kikuchi to analyze the fiber arrays of Heynecker because the system provides continuous and

Art Unit: 1743

automatic analysis of the test tape, allowing detection of analytes to be done quickly and efficiently, without the drawbacks of user intervention.

Allowable Subject Matter

6. Claims 6-8, 12 and 16 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 6-8 require a feed support system comprising a frame body having either a drum (claim 6) or a set of reels (claim 7) and an arm connected to the frame body for allowing the base member to be inserted into a vessel (such as a sample vessel). The prior art of record fails to teach or suggest a frame body having an arm attached to it, in combination with a drum or a set of reels. Also, the prior art of record fails to teach a feed pathway that forms a loop. Further, the prior art of record fails to teach a supporting member comprising detachable spacer pins that pierce through the holes of the guide frame.

Citation of Relevant Prior Art

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6,649,404 to Vann et al teach fibers having chemical species immobilized thereon. The fibers may be coiled around a hub to allow for easier detection. See figures 17-19.

Art Unit: 1743


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256.

The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jill Warden
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Technology Center 1700